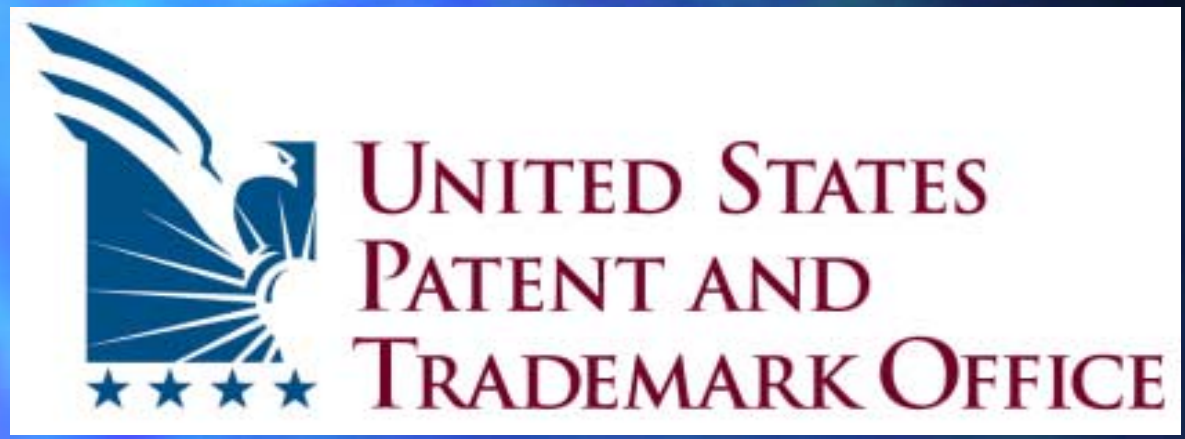

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September 11, 2000

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Patenting of Natural Products

- Background
- Why Examination Guidelines?
- Events leading to Guidelines
- Highlights of Examination Guidelines
  - 35 USC 101 Utility Guidelines
  - 35 USC 112, 1st paragraph Written Description Guidelines

Background

- Patenting compositions or compounds isolated from nature follows well-established principles and is not a new practice
  - Louis Pasteur received U.S. Patent 141,072 in 1873 claiming yeast, free from organic germs of disease, as an article of manufacture

Background Examples

- Patent for pure prostaglandins PGE_2 and PGE_3, extracted from human or animal prostate glands
  - *In re Bergstrom*, 166 USPQ 256 (CCPA 1970)
- Like other chemical compounds, DNA molecules are eligible for patents when isolated from their natural state and purified or when synthesized in a laboratory from a chemical starting material

Background

- Legislative history indicates that Congress intended “anything under the sun that is made by man” to be eligible for patenting
- Supreme Court interprets the statute to cover any “product of human ingenuity”
  - *Diamond v. Chakrabarty*, 206 USPQ 193 (1980)

Background

- A patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature
- Descriptive sequence information alone is not patentable subject matter, but a new and useful purified and isolated DNA compound described by the sequence is eligible for patenting, subject to satisfying the other criteria for patentability

Technology Center 1600

Some Current Statistics

- Over 2,300 applications have been filed having a claim drawn to an animal
- 173 animal patents have issued (87 more have been allowed)
- over 10,000 applications have been filed for entire genes (human, animal, plant)
- over 6,000 patents have issued to entire genes
- over 1,000 patents have issued to human genes
- 80 SNP patents have issued

Why Examination Guidelines?

Before Guidelines

- Consistency in examination is primary concern
- Prior to the last decade
  - MPEP was examiner's primary reference
  - Individual examiners differed in their interpretation of case law, and sometimes were not current with the law
  - High degree of uncertainty existed for examiners, as well as for practitioners, especially if MPEP was not kept current
- Instruction to examiners was done without much public comment

Why Examination Guidelines?

- USPTO decided to adopt the guidelines approach used by other large offices, such as the European Patent Office (EPO) and the Japanese Patent Office (JPO)
- Guidelines are prompted by various factors, including evolution of the law as interpreted by the Federal Circuit, particular Federal Circuit decisions which significantly impact USPTO practice, and public concerns that the USPTO should establish a more consistent approach

Why Examination Guidelines?

- USPTO creates new examination guidelines in rapidly changing areas of patent law
  - Although the guidelines don't have force and effect of law, this process;
    - Gives examiners more explicit guidance in applying the law
    - Gives both examiners and practitioners better guidance
    - Followed by training materials with specific examples

Why Examination Guidelines

- USPTO publishes its proposed guidelines and seeks public comments before finalizing the guidelines
  - 1999 Revised Interim Utility Examination Guidelines
    - Published Dec. 21, 1999 (64 Fed. Reg. 71440; 1231 O.G. 136)
    - Comment period closed March 22, 2000
  - 1999 35 U.S.C. 112 1st paragraph Written Description
    - Published Dec. 21, 1999 (64 Fed. Reg. 71427; 1231 O.G. 123)
    - Comment period closed March 22, 2000
- Guidelines and training materials are not static, but are revised as warranted by changing circumstances
- The substance of examination guidelines is incorporated into the MPEP, and therefore changes in policy/practice may be made via revisions to the MPEP

Utility Guidelines (TC 1600)

- Early 1990's
  - Biotechnology - emerging field of technology
  - Unpredictability in technology
  - **Result - Utility standard set relatively high**
- 1995 - Utility Guidelines
  - To establish consistent standards
  - Respond to concerns from the biotechnology industry over examination practices
  - Emphasis on
    - Credibility of any asserted utility
    - Evidence sufficient to demonstrate utility
  - **Result - customer/public perception that utility standard was lowered**

35 USC 101 Utility Guidelines

- 1999 Revised Interim Utility Examination Guidelines
  - Driven by extraordinary legal implications of emerging technologies, especially ESTs
  - Public queried whether disclosure of a general utility (e.g., a probe without any specific target) is sufficient
  - Guidelines emphasize requirement for *specific and substantial* credible utility
    - *Brenner v. Manson, In re Ziegler*

Three-pronged Test

- Old Test
  - Two-pronged
    - Specific
    - Credible
- New Test
  - Three-pronged
    - Specific
    - Substantial
    - Credible

Equivalents- Old v. New

- Perspective shifted from emphasizing the credibility of any specific asserted utility to determining whether an asserted utility is specific and substantial
- Many of the considerations relating to a "substantial" utility relate to the "old" considerations of "specific" utility
- "Throw away" utilities are **not** specific and substantial

Specific Utility - Definition

- A utility is *specific* when it is particular to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

Substantial Utility - Definition

- A substantial utility is one that defines a "real world" use.
  - Utilities that require carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

Substantial Utility
examples

- A therapeutic method of treating a known or newly discovered disease
- An assay method for identifying compounds that themselves have a "substantial utility"
- An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition

Substantial Utility
negative examples

- Basic research such as studying the properties of the claimed product
- A method of treating an unspecified disease
- A method of assaying for a material that itself has no specific, substantial and credible utility
- A method of making a material that itself has no specific, substantial and credible utility
- A claim to an intermediate product for us in making a final product that has no specific, substantial and credible utility

Substantial Utility vs. "Throw Away" Utilities

- **Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility.**
  - Using transgenic mice as snake food
  - Use of any protein as an animal food supplement or a shampoo ingredient
- **This analysis is tempered by consideration of the context and nature of the invention.**
  - If a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.

Credible Utility - Definition

- An assertion is credible ***unless***
  - the logic underlying the assertion is flawed, **or**
  - the facts upon which the assertion is based are inconsistent with the logic underlying the assertion
- A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use
  - For example, prevention of the aging process would not be considered a credible utility. However, nucleic acids used as probes, chromosome markers, or forensic or diagnostic markers would be considered credible.

Well Established Utility - Definition

- A specific, substantial, and credible utility which is well known, or readily apparent, based on the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art is considered a well established utility

Examination Guidelines
35 U.S.C 112, 1st paragraph
Written Description

- 1998 - Interim Guidelines
  - Prompted by *Regents of the University of California v. Eli Lilly Co.*
  - Required shift in practice with respect to descriptive support for original claims
    - Guidelines reconcile *Eli Lilly* case with decisions such as *In re Koller.*
  - Essentially limited to written description of original product claims in biotechnology arts
- Emphasis on ***how to determine possession of the invention***

Written Description Guidelines (continued)

- 1999 Revised Interim Guidelines
  - Written in **technology neutral manner** since recent decisions of the Federal Circuit have written description implications in a broad range of technologies
    - *e.g., Eli Lilly, Gentry Gallery Inc. v. Berkline Corp., Tronzo v. Biomet, Inc.*
  - Broadly applicable to all types of claims (original, new, or amended, and product, process, product-by-process)
  - Training materials also include examples from a range of technologies
  - Focus is on how to determine possession
  - Consistent with a long line of Federal Circuit decisions in clearly setting forth the burden on the examiner to establish a *prima facie* case of unpatentability

General Principles

- Basic inquiry: Can one skilled in the art reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed?

- Written description requirement is separate and distinct from the enablement requirement

General Principles

- Strong presumption that an adequate written description is present in the application as filed
- Initial burden is on examiner to establish prima facie case of unpatentability
- Applicant should show support for new or amended claims (MPEP 714.02 and 2163.06)

Methodology

- Determine what each claim as a whole covers
  - Broadest reasonable interpretation in light of and consistent with written description
    - *In re Morris*, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997)
  - Preamble and transition phrases treated under common usage
    - open: comprising, having
    - closed: consisting of
    - consisting essentially of - open to unlisted ingredients that do not materially affect the basic and novel properties of the invention

Methodology

- Review entire application to understand what applicant has described as the essential features of the claimed invention
  - Review conducted from standpoint of one of skill in the art at the time the application was filed
  - Includes determining field of invention and level of skill and knowledge in the art

Analysis

- If, on the basis of the application as filed, a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, *even if every nuance of the claim is not explicitly described in the specification*, then the requirement for an adequate written description is met.

Evidence of Possession General Principles

- What is conventional or well known to one skilled in the art need not be disclosed in detail
- There are no *per se* rules
- Allegation by examiner of unpredictability in the art is insufficient
- Need reasonable basis to challenge (description as filed is presumed adequate)

Evidence of Possession

- Written description describing sufficient relevant identifying characteristics
- Actual reduction to practice (normally not required)
- Deposit of biological materials
- Clear depiction of the claimed invention in detailed drawings

Evidence of Possession

- Possession analyzed for each claim drawn to a species, and thereafter for each claim drawn to a genus
- Written description for claimed genus may be satisfied through sufficient description of a representative number of species
  - Species must be adequately described and must fairly represent the variation within the entire genus

New or Amended Claims, or Claims Asserting Entitlement to Earlier Filing Date

- Each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure
- In some situations, minor errors in sequence information may be corrected by reliance on a deposited biological material
- Each claim must include all elements which applicant has described as essential or critical

Thank You